



ontario hydro research division

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A REVIEW OF THE REQUIREMENTS FOR ACCREDITATION OF THE ANALYTICAL SERVICES SECTION LABORATORY

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The Analytical Services Section has investigated the merits of various laboratory accreditation programs currently available. Most have been found to be either inadequate or not structured in a way to cover the multitude of tests and testing technologies that are routinely carried out. Two programs that could possibly meet the Section's requirements are offered by the Standards Council of Canada and the American Association for Laboratory Accreditation. However, the amount of work and effort required to apply for a "blanket" accreditation with either of these is immense, outweighing any advantages that might be obtained. If this topic is pursued any further, any initial application for accreditation should be for only a few selected procedures. Additional procedures could then be added in the future, if and when it is found to be desirable. The most realistic scenario is that further action be postponed until various Ontario regulatory bodies, such as the Ministry of the Environment, introduce their own accreditation programs (possibly mandatory) for specific tests or testing technologies.

1.0 INTRODUCTION

The Analytical Services Section performs a wide variety of chemical analyses on numerous types of samples for clients from throughout Ontario Hydro. Although cost and turn around time are important considerations in meeting clients' needs, the prime concern remains the accuracy and reliability of the results obtained. The key to meeting these demands is the design and implementation of an effective quality assurance (QA) program. Components of such a program have been in use within the Section for many years and were formalized into a single document in 1982/1/. This official program has been in use since that time.

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More recently, laboratory accreditation by an independent external body has come into use as an additional tool for demonstrating laboratory performance/2/. Indeed, many regulatory agencies in the United States have developed lists of approved laboratories for various analytical tests, based on their test results on submitted performance evaluation samples. Although the Ontario Ministry of the Environment does not yet use this approach, it was felt that the advent of their MISA program was likely to lead to the implementation of such a procedure in the future/3/.

In order to anticipate this requirement, the Analytical Services Section began an investigation of available accreditation programs during the latter part of 1986. This report documents the organizations evaluated and the suitability of their programs for the needs of the Section.

2.0 SUMMARY OF AVAILABLE LABORATORY ACCREDITATION ORGANIZATIONS AND THEIR PROGRAMS

2.1 Canadian Organizations

2.1.1 Canadian Testing Association (CTA)

The literature supplied by the CTA describes it as "a national Canadian association of independent, tax-paying laboratories and consultants dedicated to the advancement of independent testing and analysis, inspection and quality control and applied research". There appears to be no qualification program other than an agreement to abide by the Principles and Code of Ethics of the association. Membership would not be available to Ontario Hydro, which is of little consequence since their program does not meet the needs of the Analytical Services Section.

2.1.2 Ontario Ministry of the Environment (MOE)

As mentioned above, there was no MOE program in place at the time this investigation was started but it was felt that one could be available in the next couple of years in support of their MISA initiative. This process has in fact begun, with MOE already specifying analytical methodology, performing laboratory audits when required and analyzing duplicate samples collected for MISA.

2.1.3 Standards Council of Canada (SCC)

This is a truly national accreditation system with well documented criteria that closely match the Analytical Services Section's expectations for what such a program should entail. These include several fields of testing that cover the main

business of the laboratory. However, it appears unlikely that all of the large number of tests that are carried out by the Section can be accommodated under the Product Index currently used to classify test methods within these fields of testing. This program was investigated in more detail, as described in Section 3.1.

2.1 United States Organizations

2.1.1 American Association for Laboratory Accreditation (AALA)

This organization offers the most comprehensive program. It was formed in 1978 and is "a nonprofit, scientific, membership orientated organization that operates a national accreditation system". It appears to be more closely affiliated with the US Environmental Protection Agency (US EPA), rather than the US National Bureau of Standards (NBS). The program is based on various International Organization for Standardization / International Electrotechnical Commission (ISO/IEC) and American Society for Testing and Materials (ASTM) Standards. It covers all the work areas of the Section and most of the associated testing technologies. Its directory of accredited laboratories contains several that appear to be involved in businesses very similar to that of the Analytical Services Section. This program was also investigated in more detail, as described in Section 3.2.

2.2.2 American Industrial Hygiene Association (AIHA)

Limited information on this program was obtained from Ontario Hydro's Safety Services Department. Although some of the Analytical Services Section's work undoubtedly falls within this type of accreditation, it may be less practical to use the AIHA rather than other organizations such as the SCC or AALA.

2.2.2 US Environmental Protection Agency

The US EPA has no formal program, although evaluations are carried out on a contract by contract basis. Assistance is provided to individual States for developing lists of approved testing laboratories. The Analytical Services Section already participates in several US EPA round robins for various analyses of environmental samples.

2.2.4 US National Voluntary Laboratory Accreditation Program

This program (NVLAP) is administered by NBS and "was established in 1976 to accredit laboratories for specific tests or types of tests in certain product or service areas where a need for accreditation is determined". None of the product or service

areas presently available cover the work carried out by the Analytical Services Section, although the criteria and procedures used for the accreditation could be of use in setting up the Section's requirements.

3.0 DETAILED DESCRIPTION OF CANDIDATE ACCREDITATION PROGRAMS

3.1 Standards Council of Canada

3.1.1 Relevant Publications

The key documents in this program are the SCC publications "Accreditation Criteria and Requirements for Testing Organizations", CAN-P-4A, December 1984 and "Guidelines for Preparing an Application for Accreditation", CAN-P-1510B, December 1984. These two documents are updates of the original publication entitled "Criteria and Procedures for Accreditation of Testing Organizations", CAN-P-4, June 1978. The criteria and procedures described are considered compatible with ISO/IEC Guide 25, "General Requirements for Technical Competence of Testing Laboratories".

3.1.2 Accreditation Criteria

The five accreditation criteria addressed in CAN-P-4A include organizational base, human resources, physical resources, quality control procedures and independence of operation. A more detailed description of these criteria is given in Appendix I and they are fully discussed in CAN-P-4A. The Analytical Services Section would not experience any problems in meeting these general criteria.

3.1.3 Fields of Testing

The fields of testing available in the SCC program come under the headings of:

- Biological,
- Calibration,
- Chemical,
- Electrical,
- Mechanical,
- Nondestructive and
- Physical.

These are obviously broad enough to cover the work of almost any testing laboratory and do not present any problems for the work of the Section.

3.1.4 Product Index

The SCC program uses a Product Index to identify the types of tests for which a laboratory is accredited. This index is published in the SCC Directory of Accredited Testing Organizations, CAN-P-1550, December 1986, and is shown in Appendix II. It is this aspect of the program that is most likely to cause some problems for the Analytical Services Section. Although the Product Index contains 12 product areas consisting of 52 sub-areas and a total of 148 products, it is difficult to envision how most of the work of the Section could be categorized in this way.

3.1.5 Personal Contacts

Two of the laboratories accredited with SCC were contacted to seek their opinions on the value of the program.

The initial response of Dr. A.H. Debnam of Technical Services Laboratories, Mississauga, Ontario was that the benefits of accreditation did not warrant the effort that was required to obtain it. The necessary documentation alone required his full time attention for at least a six month period. Three fields of testing (chemical, mechanical and physical) were required to cover the range of tests they perform. The Product Index concept created enormous problems, requiring them to accredit in seven of the 12 product areas and 18 of the 52 sub-areas for a staggering total of 602 tests! Another difficulty was the relative ease of having Standard test methods accepted, such as ASTM methods, versus their more commonly used in-house procedures. The Analytical Services Section would most likely encounter the same difficulty. Dr. Debnam was not against the concept of accreditation but rather the way they had elected to apply for a "blanket" qualification for all their test methods. He felt that a much better approach would have been to list only the tests that constituted the majority of their work in their initial application. Other tests could then be added as required.

By comparison, Mr. J. Crepin of the Norwest Lab Analytical Services Laboratory, Edmonton, Alberta has found the SCC program very worth while. This was more due to the benefits of going through the process of formulizing and documenting procedures, rather than the achievement of the accreditation itself. Again, this aspect of the application required at least six months of Mr. Crepin's full time attention. Another benefit of the process was the increase in staff awareness of QA procedures, especially regarding instrument maintenance and calibration records. Unlike Technical Services Laboratories, Norwest applied for accreditation for only their most routine tests which could be

referenced to published Standard procedures. Consequently, they experienced little difficulty with the Product Index concept because they are accredited in only four of the 52 available product sub-areas identified in Appendix II, namely 1.1 Feeds, 1.2 Foods and Beverages, 9.5 Environmental Pollutants (Water Quality only) and 11.8 Soils. These sub-areas involved only 117 individual tests. Mr. Crepin was satisfied with the SCC procedures for evaluating applicants, including the laboratory audit, but felt that their lack of a supervised "round robin" program was a weakness SCC would have to overcome. Norwest Lab has a staff compliment of 20 with one person completely dedicated to QA.

3.1.6 Conclusions Regarding the SCC Program

The Analytical Services Section has over 850 different types of tests registered in its Laboratory Management System. Consequently, it is likely that similar, if not greater, problems would be encountered with the Product Index concept as were faced by Technical Services Laboratories. Any initial application made to the SCC should be for only a few selected procedures, rather than a "blanket" application. The advantages of this approach have been confirmed by other laboratories already accredited with SCC. In addition, it would seem necessary for the Section to be prepared to dedicate at least one staff member full time during the accreditation period and for the subsequent management of the resulting QA program.

3.2 American Association for Laboratory Accreditation

3.2.1 Relevant Publications

The general criteria used by AALA are from the international standard ISO/IEC Guide 25-1982, "General Requirements for the Technical Competence of Testing Laboratories" and are basically equivalent to the United States practice described in ASTM E-548-84, "Standard Practice for the Preparation of Criteria for Use in the Evaluation of Testing Laboratories and Inspection Bodies". Each applicant must agree to a set of conditions based on ISO/IEC Guide 38, "General Requirements for the Acceptance of Testing Laboratories". The procedures used by AALA for evaluating applications conform to ASTM E-994-84, "Standard Guide for Laboratory Accreditation Systems".

3.2.2 Accreditation Criteria

Guide 25 sets out general requirements for a laboratory's organization, quality system, staff, testing and measuring equipment, calibration, test methods and procedures, environment in the

laboratory, handling of items to be tested, records and test reports. AALA adds additional requirements to each of these criteria, depending on the field of testing applied for.

3.2.3 Fields of Testing

The fields of testing available in the AALA program are:

- Acoustical & Vibration Measurement,
- Biological Testing,
- Biological/Chemical (Environmental),
- Chemical Testing,
- Construction Materials Testing,
- Electrical Testing,
- Geotechnical,
- Mechanical Testing,
- Metrology,
- Non-Destructive Testing and
- Thermal.

Other more specific programs can be developed in response to user needs. Such programs may include more than one field of testing, such as the recently created Environmental program which includes both the biological and chemical fields.

Unlike the SCC program where the product index of tests is not categorized according to the fields of testing, each of the above fields leads to a specifically designed set of requirements and Testing Technologies. This appears to be a much more useful approach with the criteria matching a laboratory's tests, rather than the tests having to match the criteria.

3.2.4 Testing Technologies

AALA accredits by Testing Technologies used by a laboratory, rather than the products tested. The full list of presently available AALA Testing Technologies for the chemistry field is given in Appendix III. It contains nine main areas and 60 individual Testing Technologies. The list covers nearly all of the analyses carried out by the Analytical Services Section and most of the remaining tests could be accommodated under this type of classification. The only area not addressed at all at this time is air analysis but AALA intends to include these types of testing technologies in the future.

3.2.5 Personal Contacts

Two laboratories that are accredited for Testing Technologies similar to those used by the Analytical Services Section were

contacted to solicit their views on the AALA program.

The Analytical Services Laboratory of the Owens-Corning Fiberglass Corporation, Granville, Ohio is accredited for 39 Testing Technologies in the chemistry field. Dr. T.D. Erickson felt that the program has been extremely valuable for them because they had no QA program at all in place and suffered from lack of credibility with their clients. The achievement of the accreditation was a relatively painless procedure which was begun by an on-site inspection. A comprehensive list of requirements was generated by the inspectors which allowed any short-comings to be addressed in an orderly and logical manner. With a staff of about 50, it was necessary to appoint one full-time QA person. An interesting aspect of their credibility program is the supply of standard materials to their various clients. The clients are free to submit their standards as blind samples as often as they wish but must provide the laboratory with feed-back on the results.

The United States Army Environmental Hygiene Agency in Aberdeen, Maryland is accredited for 22 Testing Technologies in the chemistry field. According to Dr. T. Fisher, they sought accreditation with AALA mainly to qualify for US EPA awarded contracts. They were already accredited with AIHA and NIOSH and were more or less set up for the AALA program before their application in 1984. They have 12 persons devoted to their QA program out of a staff of 585. Dr. Fisher pointed out that the AALA accreditation has now become less important because State Government's have developed or are in the process of setting up their own programs to produce lists of approved testing laboratories.

3.2.6 Conclusions Regarding the AALA Program

In summary, the AALA program appears to be best suited to the requirements of the Analytical Services Section. This is unfortunate as it would obviously be desirable to accredit with a Canadian organization. The main reason the AALA program is preferred is because of its use of the more flexible Testing Technologies approach, as opposed to the Product Index concept used by the SCC. This facilitates a "blanket" application approach for all the work of the Section. However, it does not significantly reduce the amount of effort that would be required during and following accreditation. Indeed, the AALA criteria state that "A person or persons having responsibility for quality assurance within the laboratory shall be designated by the laboratory management and shall have direct access to top management", making it virtually mandatory to have dedicated and independent QA personnel.

4.0 SUMMARY AND RECOMMENDATIONS

Only two of the seven organizations investigated were found to offer accreditation programs of potential use to the Analytical Services Section. Of these two, the American Association for Laboratory Accreditation (AALA) appears to have the most comprehensive and flexible program that is best suited for the large number and wide variety of tests carried out by the Section. This is mainly due to their use of Testing Technologies rather than individual analyses to define the tests being accredited. The other program, offered by the Standards Council of Canada, is weakened by their use of a Product Index to define the tests performed by a laboratory. It is difficult to see how this approach could be used to classify all the different analyses carried out by the Analytical Services Section.

The above assessment is based on the assumption that the Section would be applying for a "blanket" accreditation that would cover most, if not all, of the laboratory's tests. The amount of work required to prepare and carry through such an application appears to be immense and would likely cause a serious disruption in the productivity of the laboratory during that period. This has been confirmed by personal contact with four laboratories that have already undergone accreditation, two with AALA and two with SCC. All four agreed that best approach would be to initially apply to accredit only a few tests that constitute either a majority of a laboratory's work or involve analyses that will be used to determine if materials or products meet critical specifications. Both the AALA and SCC programs would be suitable for this purpose.

It is interesting to note that out of the four laboratories contacted, the two most positive responses regarding accreditation came from those that had little or no QA procedures in place at the time of application. In effect, the accreditation process was used to force an acceptable QA program to be implemented. This would not be applicable to the Analytical Services Section since such a program is already in place.

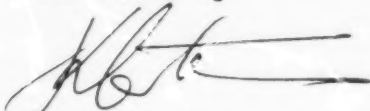
Finally, it would appear that the usefulness of accrediting with an independent organization in the United States is likely to be limited in the future as individual States develop (with the aid of the US EPA) their own programs. It is likely that the Ontario Ministry of the Environment (MOE) will also follow this approach.

Therefore, it is recommended that the Analytical Services Section take no further action at this time regarding laboratory accreditation. Accreditation should be applied for only if and when the MOE implements a program, and initially only for those tests that are required to support programs such as MISA.

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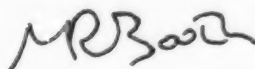
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2. Locke, J.W., Environ. Sci. Technol., Vol. 21, No. 4 (1987) p332.
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APPENDIX I

Accreditation Criteria used by the Standards Council of Canada

1. **Organizational Base:** The organization shall have an administrative system capable of operating and maintaining the testing activity for which it is accredited.
2. **Human Resources:** The organization shall be managed by people knowledgeable of test standards and test methods and professionally qualified to maintain records, manage and operate the testing activity for which it is accredited, and provide adequate reports.
3. **Physical Resources:** The organization shall have adequate facilities and equipment to carry out the testing activity for which it is accredited.
4. **Quality Control Procedures:** The organization shall have documented and acceptable quality control procedures to ensure its integrity of its accredited testing activity.

These procedures cover:

Sample control, storage and disposition

Test data, test reports and records

Measurement accuracy

Quality control documents

Monitoring of test work

Technical documents

Settlement of complaints.

5. **Independence of Operation:** The organization, if subject to direct influence due to manufacturer or supplier interest, shall have acceptable procedures to ensure its objectivity and independence from such interests.

APPENDIX II

Product Index used by the Standards Council of Canada

1.0 AGRICULTURAL PRODUCTS

- 1.1 Feeds:
 - Mineral
 - Mixed
- 1.2 Foods and Beverages:
 - Cereals and Grains
 - Dairy Products
 - Fruits
 - Generally Applicable Tests
 - Meats and Nuts
 - Miscellaneous

2.0 CALIBRATION OF MEASURING AND TEST EQUIPMENT

- 2.1 Electrical and Electronic Properties:
 - Base Units
- 2.2 Physical Properties:
 - Length, Mass, Surface and Volume
 - Pressure, Temperature and Time

3.0 CHEMICALS AND CHEMICAL PRODUCTS

- 3.1 Undefined
- 3.2 Chemical Compounds:
 - Inorganics
 - Organics

4.0 CONSTRUCTION AND RELATED MATERIALS

- 4.1 Undefined
- 4.2 Building Materials:
 - Caulking, Sealing and Glazing Compounds
 - Ceiling Coverings
 - Fasteners and Hardware
 - Floor Coverings
 - Insulating Materials
 - Miscellaneous Materials
 - Panels, General Purpose
 - Plumbing Products and Materials

Roof Coverings
Wall Coverings
Windows and Doors

4.3 Undefined

4.4 Prefabricated Assemblies:
Cabinets
Ventilation Equipment

4.5 Undefined

4.6 Trades Work:
Welding

5.0 ELASTOMERS AND PROTECTIVE COATINGS

5.1 Adhesives and Sealants:
Adhesives
Miscellaneous Materials
Sealants

5.2 Plastics:
Composites
Compounds
Foams
Parts and Products

5.3 Undefined

5.4 Protective Coatings, Vehicles and Pigments:
Applications and Working Properties
Applied Coatings Performance
Colour and Appearance
Constituents

5.5 Rubber and Resins:
Miscellaneous Materials
Polymers, Resins and Organic Materials

6.0 ELECTRICAL AND ELECTRONIC PRODUCTS

6.1 Undefined

- 6.2 Appliances:
 - Cooking and Liquid Heating
 - Heating, Refrigeration and Air Conditioning
 - Luminaires and Fixtures
 - Miscellaneous
 - Motor Operated
 - Washing Equipment
- 6.3 Communications Equipment and Systems:
 - Broadcasting
 - Components and Assemblies
 - Radio, Television and Electronic Apparatus
 - Signal Equipment
 - Telecommunications Terminal Equipment
- 6.4 Components and Assemblies:
 - Circuit Breakers and Fuses
 - Rectifiers
 - Switches and Controls
 - Transformers
- 6.5 Information Processing and Business Equipment:
 - Data Processing Equipment
 - Office machines
- 6.6 Laboratory Equipment:
 - Complete units
 - Switches and Controls
- 6.7 Materials:
 - Miscellaneous
 - Plastics
- 6.8 Miscellaneous Equipment:
 - Conductors
 - Enclosures
 - Generally Applicable Tests
 - Grounding
 - Insulators
 - Panels
- 6.9 Motors, Generators and Machines:
 - Complete Unit
- 6.10 Power and Signal Distribution Equipment:
 - Wiring and Related Products

7.0 MECHANICAL MACHINERY

7.1 to 7.5 Undefined

7.6 Miscellaneous Machinery:
Portable Utility Engines
Pumps and Related Equipment

7.7 Undefined

7.8 Stationary Equipment:
Hoists

7.9 Transportation Vehicles and Components:
Automobiles, Light Trucks, Vans and Trailers
Boats and Ships
Generally Applicable Tests
Recreational, All-Terrain
Trucks, Heavy Duty, Commercial, Buses and Trailers

8.0 METALLIC ORES AND PRODUCTS

8.1 Undefined

8.2 Metallic Ores and Minerals:
Precious Metals
Rocks and Ores
Sediments

8.3 Metal Powders:
Formulations

8.4 Metals:
All Forms
Components

9.0 MISCELLANEOUS PRODUCTS AND MATERIALS

9.1 Consumer Articles:
Hazardous Products
Household Products
Photocopying and Related Equipment
Sports Equipment
Tools
Toys

9.2 Undefined

- 9.3 Energy Equipment:
 - Handling of Liquid Fuels
 - Kerosine Fired Appliances
 - Miscellaneous
 - Oil Fired Appliances
 - Propane Fired Appliances
 - Solid Fuel Fired Appliances
- 9.4 Environmental Factors:
 - Marine Conditions
 - Meteorological Conditions
- 9.5 Environmental Pollutants:
 - Biological Materials Quality
 - Water Quality
- 9.6 Undefined
- 9.7 Medical and Health Care Equipment:
 - Breathing Apparatus and Equipment
 - First Aid
 - Packaging Materials
 - Treatment Equipment
- 9.8 Munitions:
 - Military Small Arms
- 9.9 Nuclear Radiation and Shielding:
 - Emitting Equipment
- 9.10 Undefined
- 9.11 Safety Devices and Supplies:
 - Biohazard Cabinetry
 - Clean Air Devices
 - Occupational Health and Safety
 - Personal Protection
 - Warning Devices
- 9.12 Undefined
- 9.13 Trade and Commercial Goods:
 - Containers and Packaging
 - Packaging Components and Materials

10.0 NONDESTRUCTIVE TESTING SERVICES

10.1 Liquid Penetrant:

10.2 Magnetic Particle:

10.3 Radiographic:

10.4 Visual, Welding:

11.0 NONMETALLIC MINERALS AND PRODUCTS

11.1 Cement and Products:
Composites and Types
Products

11.2 Ceramics and Clays:
Bricks and Structural Tile, Clay
Ceramics
Clays
Porcelain Enamels
Refractory and Firebrick

11.3 Undefined

11.4 Geological Surveys:
Constituents
Methods

11.5 Glass:
Constituents and Formulations
Glassware

11.6 Lime and Gypsum:
Gypsum
Lime

11.7 Refined Petroleum:
Asphalt
Fuels and Lubricants
Petrochemicals

11.8 Soils:
Constituents and Nutrients
Physical Parameters

11.9 Solid Fuels and By-Products:
Miscellaneous
Peat

12.0 TEXTILES AND FIBROUS MATERIALS

12.1 Clothing and Other Finished Articles:

Clothing
Floor Coverings
Furniture Coverings
Mattresses
Tents

12.2 Wooden and Wood-Based Products:

Composites
Finished Wood
Generally Applicable Tests
Lumber
Plywood
Prefabricated Components
Wood Products, General

12.3 Paper and Allied Articles:

Paper and Paperboard
Paper Products

12.4 Textiles:

Fabrics
Fibres
Generally Applicable Tests
Yarns

APPENDIX III

Testing Technologies used by the American Association for Laboratory Accreditation

The following is a list of the Testing Technologies currently in use by AALA for laboratory accreditation in the Chemistry Field of Testing.

1. Chromatography

- Gas chromatography
- GC/Infra red
- GC/Mass spectrometry
- Gel permeation chromatography
- High performance liquid chromatography
- Ion chromatography
- Paper chromatography
- Thin layer chromatography

2. Electrochemistry

- Polarography
- Potentiometric analysis

3. Microscopy

- Auger electron microscopy
- ESCA
- Optical microscopy
- Quantitative image analysis
- Scanning Auger microprobe
- Scanning electron microscopy
- Scanning transmission electron microscopy
- Transmission electron microscopy

4. Physical properties

- Colligative properties
- Density
- Particle size
- Porosity
- Turbidity
- Viscosity

5. Radioactivity Measurements

- Gamma counting
- Liquid scintillation counting
- Proportional counting
- Various radiochemical analyses

6. Spectroscopy

- Atomic absorption - flame
- Atomic absorption - furnace
- Emission - flame
- Emission - arc/spark
- Emission - ICP
- Fluorescence
- Infra red
- Mass spectrometry
- Nuclear magnetic resonance
- Raman
- Ultra violet spectrophotometry
- Visible spectrophotometry
- X-ray diffraction
- X-ray fluorescence - Energy dispersive
- X-ray fluorescence - Wavelength dispersive

7. Thermal Analysis

- Ash fusion
- Calorimetry
- Differential scanning calorimetry
- Differential thermal analysis
- Dynamic mechanical analysis
- Fusibility
- Thermal gravimetric analysis
- Thermal mechanical analysis

8. Wet Chemical

- Calorimetry
- Gravimetry
- Titrimetry

9. Miscellaneous

Autoanalysis
Biological oxygen demand
Conductivity
Specific ion electrode analysis
Total organic carbon
Total organic halogen